CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
75-456/458

BIOEQUIVALENCE

Enalaprilat | **Abbott labs**
1.25 mg/mL I.V. injection (VIAL) | Abbott Park, Il 600643537
ANDA # 75-458 | Submission Date:
Reviewer: Pradeep Sathe | November 23, 1998
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Review of a Bioequivalence Study Waiver Request

Category: ACE inhibitor.

Indication: Treatment of hypertension when oral therapy is not practical

RLD: Vasotec® 1.25 mg/mL injection (VIAL) by Merck & Co.

Possible First Generic: Yes

Formulation Composition:

INGREDIENTS	TEST **mg/mL**	REFERENCE **mg/mL**
Enalaprilat	1.25	1.25
Sodium Chloride		
Benzyl Alcohol	9	9
Sodium Hydroxide to adjust to pH		
Water		

The injection is filled as a 1 mL fill in 2 mL vial and 2 mL fill in 2 mL vial.

COMMENTS:

1. Enalarpilat is the active ingredient. Benzyl alcohol is a preservative, sodium chloride is the isotonicity adjuster and sodium hydroxide is for adjusting pH to

2. The active ingredient, route of administration, dosage form and strength for Enalaprilat injection is same as those of the innovator product Vasotec® 1.25 mg/mL injection by Merck & Co. The concentration of sodium chloride in the RLD is mg/ml while in the test it is .; a difference of mg/ml which amounts to less than The test product is therefore considered to have essentially similar Q and Q.

3. The indications and end use is identical to the innovator formulation.

RECOMMENDATION:

The Division of bioequivalence agrees that the information submitted by Abbott Labs. Demonstrates that Enalaprilat 1.25 mg/mL I.V. injection falls under 21 CFR section 320.22 (b)(1) of the Bioavailability/Bioequivalence regulations. The waiver of in-vivo bioequivalence study for Enalaprilat 1.25 mg/mL I.V. injection of the test product is granted. From the bioequivalence point of view, the Division of Bioequivalence deems the test injectable formulation to be bioequivalent to Vasotec® 1.25 mg/mL injection manufactured by Merck & Co.

Pradeep M. Sathe, Ph.D.
Division of Bioequivalence
Review Branch II

RD INITIALED SGNerurkar, Ph.D.
FT INITIALED SGNerurkar Date 1/11/1999

Concur: Dale P. Conner Date 1/11/99
Dale P. Conner, Pharm.D.
Director, Division of Bioequivalence

Enalaprilat
1.25 mg/mL I.V. injection (carpuject)
ANDA # 75-456
Reviewer: Pradeep Sathe
X:\new\firmsal\abbott\ltrs&rev\75456W.N98.doc

Abbott labs
Abbott Park, Il 600643537
Submission Date:
October 28, AR
~~November 28~~, 1998

Review of a Bioequivalence Study Waiver Request

Category: ACE inhibitor.

Indication: Treatment of hypertension when oral therapy is not practical

RLD: Vasotec® 1.25 mg/mL injection by Merck & Co.

Possible First Generic: Yes

Formulation Composition:

INGREDIENTS	TEST **mg/mL**	REFERENCE **mg/mL**
Enalaprilat	1.25	1.25
Sodium Chloride Benzyl Alcohol	9	9
Sodium Hydroxide to adjust to pH Water for Injection q.s.		

The innovator product is marketed only in vials. Abbott is marketing this product in a syringe (carpuject).

COMMENTS:

1. Enalarpilat is the active ingredient. Benzyl alcohol is a preservative, sodium chloride is the isotonicity adjuster and sodium hydroxide is for adjusting pH

2. The active ingredient, route of administration, dosage form and strength for Enalaprilat injection is same as those of the innovator product Vasotec® 1.25 mg/mL injection by Merck & Co. The concentration of sodium chloride in the RLD is mg/ml while in the test it is ng/ml; a difference of mg/ml which amounts to less than The test product is therefore considered to have essentially similar Q and Q.

3. The indications and end use is identical to the innovator formulation.

RECOMMENDATION:

The Division of bioequivalence agrees that the information submitted by Abbott Labs. Demonstrates that Enalaprilat 1.25 mg/mL I.V. injection (carpuject) falls under 21 CFR section 320.22 (b)(1) of the Bioavailability/Bioequivalence regulations. The waiver of in-vivo bioequivalence study for Enalaprilat 1.25 mg/mL I.V. injection of the test product is granted. From the bioequivalence point of view, the Division of Bioequivalence deems the test injectable formulation to be bioequivalent to Vasotec® 1.25 mg/mL injection manufactured by Merck & Co.

1/11/99

Pradeep M. Sathe, Ph.D.
Division of Bioequivalence
Review Branch II

RD INITIALED SGNerurkar, Ph.D.
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Dale P. Conner, Pharm.D.
Director, Division of Bioequivalence